REMARKS

Claim 1 to 13, 15, 16 and 18 to 23 are in the application. Claims __ have been amended to remove a typographical error or to separate the compounds due to the election of species. No new matter is believed added.

The Examiner has restricted the claims into three groups as shown below:

Group I, claims 1-13, 19-22, drawn to a compound of formula I.

Group II, claims 15-16, drawn to a method for treating a condition or disease state mediated by p38 kinase activity or mediated by cytokines produced by the activity of p38 kinase.

Group III, claims 18, drawn to a process for preparing a compound of formula I.

The Examiner basis for this restriction is that Groups I-III do not relate to a single inventive concept under PCT Rule 13.1 because under PCT Rule 13.2 they lack the same or corresponding technical feature for the following reasons: the claims of Group I are directed to a pharmaceutical composition whereas the claims in Group II are directed to a method and the claims of Group III are directed to a process of making.

A common technical feature does exist, and the Examiner is improperly applying US restriction practice to an international derived application.

The MPEP and Annex B to the PCT rules deal with the application of Rule 13.2 and the unity of invention standard as it applies to Markush practice. Thus, with respect to a Markush group, unity of invention is fulfilled if:

> (A) all alternatives have a common property, and
> (B)(1) a common structure is present, i.e., a significant structural element is shared by all of the alternatives, or
> (B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.
> MPEP ¤ 1850

In the instant application both (A) and (B)(1) are met. The alternative share the same common properties (A), a phenyl bonded to a heteroaryl ring. The structural features are the same scope in both Group I –Group III. These groups all stem from a

common research and development program. A combination of features clearly represents a significant structural element of the compounds as defined in the MPEP, *e.g.*, "[t]he structural element may be a single component or a combination of individual components linked together." *See* MPEP ¤ 1850 (1800-50). It is noted that the Examiner has asserted distinctiveness (*e.g.*, different issues of novelty and unobviousness), and that a separate search of the different groups are criteria which support restriction of the instant application. The MPEP speaks dispositively to the applicability of separate classification and search to unity when it states that "[t]he fact that the alternatives of a Markush grouping can be differently classified shall not, taken alone, be considered to be justification for a finding of a lack of unity of invention." *See* MPEP ¤ 1850 (1800-50).

The Examiner has not substantiated that there is, or will be separate classification in the art for these two groups. Similarly, the Examiner has not substantiated that there is or will be a different field of search which must take place for these two groups.

The instant invention was filed under the provisions of 35 U.S.C. §371 as a national stage filing of PCT patent application. Thus, the standard applicable to the instant application is not one of restriction practice under U.S. guidelines, but of Unity of Invention under the PCT. *See* MPEP § 1895.01 (4). In the instant case no lack of Unity of Invention was found by the International Searching Authority or the International Preliminary Examining Authority. All the claims were searched and examined as one invention in the PCT. Since the Markush grouping is proper, Applicants respectfully request that the USPTO reconsider and withdraw the restriction requirement, and provide notice of allowance of all the claims in a single application.

The question of Unity of Invention may be re-examined only within the scope of rules of the Patent Cooperation Treaty (35 U.S.C. § 372(b)), and restriction requirements made according to U.S. practice, which are more restrictive that the PCT regulation are in error. Patent Cooperation Treaty, Art. 27 ("no national law shall require compliance with requirements relating to form or contents ... different from or additional to those which are provided for this Treaty and the Regulations").

Therefore, the Examiner must find error in the application of the rules by the International Search Authority. There is no allegation in the outstanding Office Action indicating that the International Search Authority committed an error in applying the rules for Unity of Invention.

The reasons given for the instant restriction requirement pertain only to U.S. practice since they are based primarily on distinctiveness. PCT Rule 13.1 includes within the definition of Unity of Invention "a group of inventions so linked as to form a general inventive concept." Accordingly, patentably distinct inventions do not lack Unity of Invention as long as they derive from the same inventive concept. Consequently, distinctiveness, as used in U.S. practice, is not a sufficient criterion for a holding of lack of Unity of Invention or for a restriction requirement under 35 U.S.C. 372(b).

Moreover, PCT Rule 13.2 specifically states that the requirement of Unity of Invention is fulfilled "when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features". The Examiner requires restriction according to U.S. practice, but this conflicts with PCT Rule 13.2 and must give way to the PCT rule.

Consequently, it is believed that this restriction is not appropriate and Applicants request that all the claims in the application be examined together.

However, in order to respond to the Examiner request, Applicants elect Group I with traverse. The Examiner has also requested an election of species. Applicants elect for A, a fused 5 membered heteroaryl ring corresponding to a pyrrolyl and the fused heteroaryl ring corresponding to an indazole., and more specifically the compound of Example 1, *N*-Cyclopropyl-3-fluoro-4-methyl-5-(1-phenyl-1*H*-indazol-5-yl)benzamide. More generically, the A ring is substituted by an optionally substituted –(CH2)m aryl moiety, and R2 is a C(O)NH-(CH2)1-R7 moiety. Claims 1 to 4, 8 to 13 read upon this election. Claim 11 has been amended to list on indazole species, the remaining compound of originally filed claim 11 now being presented in newly added claim 23.

Should the Examiner have any questions or wish to discuss any aspect of this case, the Examiner is encouraged to call the undersigned at the number below. If any

additional fees or charges are required by this paper the Commissioner is hereby authorized to charge Deposit account 19-2570 accordingly.

Respectfully submitted,

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